EXHIBIT 3

[Group 2 Deficient Complaints]

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEAST DIVISION

ELIZABETH BRAY, Plaintiff, v. AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SPECIALTY SURGERY CENTER, PLLC, DR. KENNETH R. LISTER, Defendants.	)	Case No. JURY DEMAND

COMPLAINT

The Plaintiff, Elizabeth Bray, for her cause of action against the defendants respectfully states to the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of the widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 200 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as

"MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff Elizabeth Bray and for many others who have suffered serious and at times catastrophic injuries.

4. During the period June through August 2012, Specialty Surgery Center, PLLC ("Specialty Surgery Center") purchased approximately 220 vials of MPA from NECC and then sold and administered the MPA to patients including Elizabeth Bray.

5. On September 20, 2012, Elizabeth Bray received a lumbar epidural steroid injection ("ESI") at Specialty Surgery Center. During that procedure the anesthesiologist injected 80 mg/mL of MPA into Elizabeth Bray's lower back.

6. On information and belief, Elizabeth Bray's September 20, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

7. Elizabeth Bray's September 20, 2012 injection of MPA caused possible inflammation at the site of her injection and caused her to undergo a lumbar puncture.

PARTIES

8. Plaintiff Elizabeth Bray is a citizen and resident of Tennessee and resides at 214 Sneed Drive, Crossville, Tennessee 38552.

9. Defendant Ameridose, LLC ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581. Ameridose is owned by defendants Carla Conigliaro, Barry Cadden, Lisa Cadden, and Gregory

Conigliaro. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President of MSM. Defendant, Barry Cadden, is the Treasurer of MSM. Defendant, Gregory Conigliaro is the Secretary of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director, Gregory Conigliaro is the Secretary and Director and Lisa Conigliaro Cadden is Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden was a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden was the Treasurer and Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of

Massachusetts. Mr. Conigliaro is the President and Director of MSM and MSMSW. Mr. Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 is a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and is a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC.

20. Defendant Specialty Surgery Center, PLLC ("Specialty Surgery Center") is a Professional Limited Liability Company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery Center's principal place of business is 116 Brown Avenue, Crossville, Tennessee 38555. Specialty Surgery Center's registered agent for service of process is Donathan M. Ivey, 116 Brown Avenue, Crossville, Tennessee 38555.

21. Defendant Kenneth R. Lister, M.D. ("Dr. Lister") is an individual residing at 8317 Neubert Springs Road, Knoxville, TN 37920 and is a citizen and resident of the State of Tennessee. During all relevant times, Kenneth Lister was an employee of Specialty Surgery Center. Kenneth Lister is a medical doctor and practices in the specialty of anesthesiology. Kenneth Lister was involved in the day to day operations at Specialty Surgery Center.

22. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the "NECC Related Defendants."

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.§ 1334(b) because as described herein each claim asserted herein is related to a case under Title 11

of the United States Bankruptcy Code (the "Bankruptcy Code"). Specifically, on December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code. This case is pending in the United States Bankruptcy Court for the District of Massachusetts and is styled as *In re: New England Compounding Pharmacy*, Case No. 12:12-19882 HJB (the "Bankruptcy Proceeding"). The Bankruptcy Court has appointed a bankruptcy trustee to administer the Bankruptcy Estate.

24. Further, as a result of the large number of actions arising from the NECC-related meningitis outbreak, On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS (the "MDL Proceeding"). The MDL Proceeding has been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

25. The Bankruptcy Court has not yet set a deadline for filing of claims against NECC's estate. Plaintiff will submit a timely claim in the Bankruptcy Proceeding at the appropriate time.

26. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. On information and belief, some if not all of the aforementioned individuals are insureds under

NECC's insurance policies. All aforementioned individuals and entities are NECC Related Defendants as that term is used throughout this Complaint.

27. Adversarial cases seeking damages for the benefit of the Bankruptcy Estate and its unsecured creditors have been filed in the Bankruptcy Proceeding against each of the NECC Related Defendants.

28. On information and belief, Specialty Surgery Center will file a claim in the Bankruptcy Proceeding seeking contribution, indemnity, and/or breach of warranty damages from NECC Bankruptcy Estate and will seek relief from the automatic stay provided for in 11 U.S.C. § 362.

29. By Order dated May 31, 2013, Judge Saylor in the MDL Proceeding ruled that federal courts have subject matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC, whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the NECC Related Defendants. Accordingly, this action falls within the ruling of this May 31, 2013 Order, and this Court has subject matter jurisdiction over this action.

30. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject matter jurisdiction over all claims against Specialty Surgery Center and Dr. Lister pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

31. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the

events and actions giving rise to the matters asserted in the Complaint occurred in this jurisdiction.

32. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

33. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Massachusetts that have proximately caused the injuries that are the subject of this lawsuit.

34. The NECC Related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

Relevant Background

35. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

36. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

37. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

38. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

39. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

40. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

41. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

42. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

43. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

44. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

45. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians

employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

46. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC.

47. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

48. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

49. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

50. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

51. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

52. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

Claims Against the NECC Related Defendants

53. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

54. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa

Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regard to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

55. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided the New England Compounding Center's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

56. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.

57. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

58. Eighty-three out of 321 observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All 50 out of 50 vials tested confirmed the presence of live microbes

(whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least 40 fungal meningitis cases.

59. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least 53 instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

60. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

61. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (MPA) 80 mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

62. NECC identified Specialty Surgery Center in Crossville, Tennessee as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.

63. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

64. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

65. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

66. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

67. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

68. According to its Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

69. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding

pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

70. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

71. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. ***You should expect nothing less from the testing laboratory you entrust.***" (emphasis in original)

72. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "***[t]esting methods and technologies [are] unparalleled in the market today[.]***" (emphasis in original)

73. With respect to its sterility tests, ARL, on its website, stated: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

74. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

75. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml

vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

76. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

77. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

78. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

79. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

80. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

81. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68

to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

82. ARL was aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

83. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

84. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

85. In 2007, Mr. Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

86. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding," which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

87. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Mr. Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results," Mr. Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

88. While the requirements of USP 71 were not relaxed for compounding pharmacies after Mr. Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

89. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

90. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

91. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Ensure all tenants operate their businesses in accordance with facility, local [and] state...rules and regulations."

92. GDC maintained a high degree of control over the premises leased by NECC.

93. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.

94. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

NECC and the Risks of Pharmacy Compounding

95. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. In other words, the risks associated with compounded drugs have been known for years.

96. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that…follows appropriate measures to ensure that injectable products are free of contamination."

97. On March 24, 2005, *USA Today* published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

98. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

99. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

100. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

101. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
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> . . .
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> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

102. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

The Fungal Meningitis Outbreak

103. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

104. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of ESIs at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health, contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

105. Dr. Kainer told personnel at St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received ESIs at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

106. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

107. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.

108. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

109. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

110. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of

the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might have just one or two of these symptoms.

Elizabeth Bray is Injected with MPA from NECC and Experiences Adverse Health Effects

111. On September 20, 2012, Elizabeth Bray received a lumbar ESI at Specialty Surgery Center. During that procedure the anesthesiologist injected 80 mg/mL of MPA into Elizabeth Bray's lower back.

112. On information and belief, Elizabeth Bray's September 20, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

113. Elizabeth Bray's September 20, 2012 injection of MPA caused her adverse health effects.

114. On or around October 5, 2012 Elizabeth Bray developed headache, nausea, vomiting, weakness and dizziness.

115. On October 4, 2012 Elizabeth Bray presented to the Cumberland Medical Center emergency room. On October 4, 2012, Elizabeth Bray had a lumbar puncture and lumbar MRI. The lumbar MRI was normal, but the lumbar puncture could not be completed. Elizabeth Bray was transferred to Cookeville Regional.

116. Elizabeth Bray was admitted to Cookeville Regional Medical Center on October 5, 2012, where she received another lumbar puncture.

117. Elizabeth Bray remained at Cookeville Regional Medical Center until she was discharged on October 8, 2012. Elizabeth Bray was treated with antifungal VFEND as a precaution.

118. On information and belief, the MPA injected into Elizabeth Bray's lumbar spine came from one or more of the three recalled contaminated lots.

119. As a direct and proximate result of the contaminated ESIs, Elizabeth Bray had symptoms of meningitis, received two lumbar punctures and was hospitalized for four days.

CAUSES OF ACTION

COUNT I
NEGLIGENCE
(Against NECC Related Defendants)

120. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

121. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC related Defendants owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Plaintiff Elizabeth Bray.

122. Specifically, but without limitation:

a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Plaintiff a duty to properly conduct tests to ensure that the methylprednisolone acetate was safe and free of contamination.

123. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and

agents, engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

124. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Plaintiff.

125. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

126. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Plaintiff's injuries.

127. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into her in September 2012.

128. As a direct and proximate result of the negligence of these Defendants, and being injected with contaminated doses of methylprednisolone acetate, Elizabeth Bray has suffered injuries and damages including, but not limited to, pain and suffering, emotional distress, anxiety, emotional damage, and has incurred medical and other expenses. Such damages render her no longer able to engage in her daily activities and enjoyment of life.

COUNT II
NEGLIGENCE PER SE
(Against NECC Related Defendants)

129. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

130. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

131. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

132. Defendants also violated Massachusetts law and its pharmacy licensing obligations.

133. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Elizabeth Bray has suffered injuries and damages as described with particularity, above.

COUNT III
NEGLIGENT SUPERVISION
(Against NECC Related Defendants)

134. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

135. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to

investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

136. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

137. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

138. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff, Elizabeth Bray.

139. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Elizabeth Bray has suffered injuries and damages as described with particularity, above.

COUNT IV
PUBLIC NUISANCE

(Against Barry Cadden, Gregory Conigliaro and GDC)

140. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

141. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

142. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

143. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

144. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

145. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

146. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

147. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Plaintiff's injuries.

148. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Elizabeth Bray special injury in that Elizabeth Bray has sustained injuries to her personal health.

149. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Elizabeth Bray has suffered injuries and damages as described with particularity, above.

COUNT V
DECEPTIVE TRADE PRACTICES ACT
(Against NECC Related Defendants)

150. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

151. The NECC Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

152. The NECC Related Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act. The NECC Related Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

153. As described herein, the NECC Related Defendants represented that their product had characteristics, uses and benefits that it did not have.

154. As described herein, the NECC Related Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

155. The NECC Related Defendants failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use NECC Related Defendants' product.

156. The NECC Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Plaintiff, constituting a violation of the Act.

157. The NECC Related Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

158. The NECC Related Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

159. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

160. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiff.

161. The NECC Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the product;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

162. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally, the NECC Related Defendants were unethical and unscrupulous, and caused substantial injury to consumers. The NECC Related Defendants engaged in unconscionable actions and course of action.

163. The NECC Related Defendants willfully engaged in the conduct described herein, which they knew was deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

164. The NECC Related Defendants are liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

COUNT VI
PRODUCT LIABILITY CLAIMS
(Against Specialty Surgery Center and Dr. Kenneth Lister)

165. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

166. The MPA injected into Elizabeth Bray's lumbar spine on September 20, 2012 was compounded by NECC.

167. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (Eastern Division) No. 12-19882-HJB.

168. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

169. Plaintiff could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

170. Plaintiff's claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

171. NECC has ceased operations.

172. NECC is unable to pay its debts as they fall due.

173. NECC is unable to pay its debts in the ordinary course of its business.

174. NECC's liabilities exceed its assets.

175. NECC is insolvent as declared by order dated July 24, 2013 in the Bankruptcy Proceeding.

176. Specialty Surgery Center procured the MPA injected into Elizabeth Bray's lumbar spine from NECC.

177. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery Center injected it into Elizabeth Bray's lumbar spine on September 12, 2012.

178. Specialty Surgery Center charged Elizabeth Bray for ESIs administered to Elizabeth Bray.

179. Specialty Surgery Center acted as a seller or distributor of MPA compounded by NECC when it sold and administered ESIs to patients, including Elizabeth Bray.

180. Specialty Surgery Center was engaged in the business of selling MPA compounded by NECC.

181. Accordingly, Specialty Surgery Center is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

182. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiff Elizabeth Bray to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA injected into Elizabeth Bray's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.

183. The MPA that Specialty Surgery Center injected into Elizabeth Bray's lumbar spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

184. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

185. The MPA sold and distributed by Specialty Surgery Center was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery Center breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

186. Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Elizabeth Bray's lumbar spine.

187. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act, T.C.A. § 29-26-101, *et. seq*. Plaintiff has served notice letters as required by the TMMA, but sixty days haven not yet passed since service of those letters. Plaintiff files this action to preserve her products liability action, and will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

DAMAGES

188. As a direct and proximate result of the Defendants' wrongful conduct as described above, Elizabeth Bray has suffered physical injuries, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.

189. The long term effects of Elizabeth Bray's illness are unknown.

190. Elizabeth Bray has incurred and continues to incur medical and other expenses.

PUNITIVE DAMAGES

191. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiff therefore is entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

192. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiff's non-economic damages are purportedly capped at $750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.

193. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiff's constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense

whatever...and shall forever remain inviolate." Therefore, Elizabeth Bray requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

194. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiff is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Elizabeth Bray requests the following relief:

A. A judgment to plaintiff for compensatory damages in excess of $75,000;

B. A judgment for punitive damages in an amount to be determined by the trier of fact;

C. A jury to determine all disputed factual issues;

D. For costs of this cause and reasonable attorneys' fees; and

E. For such further relief as the Court may deem just and proper.

Respectfully submitted,

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Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEAST DIVISION

JUDY COLLINS, Plaintiff, v. AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SPECIALTY SURGERY CENTER, PLLC, DR. KENNETH R. LISTER, Defendants.	)	Case No. JURY DEMAND

COMPLAINT

The Plaintiff, Judy Collins, for her cause of action against the defendants respectfully state to the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of the widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 200 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of

preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as "MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff Judy Collins and for many others who have suffered serious and at times catastrophic injuries.

4. During the period June through August 2012, Specialty Surgery Center, PLLC ("Specialty Surgery Center") purchased approximately 220 vials of MPA from NECC and then sold and administered the MPA to patients including Judy Collins.

5. On September 12, 2012, Judy Collins received a lumbar epidural steroid injection ("ESI") at Specialty Surgery Center. During that procedure the anesthesiologist injected 80 mg/mL of MPA into Judy Collins's lower back.

6. On information and belief, Judy Collins's September 12, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

7. Judy Collins's September 12, 2012 injection of MPA caused possible inflammation at the site of her injection and caused her to undergo a lumbar puncture.

PARTIES

8. Plaintiff Judy Collins is a citizen and resident of Tennessee and resides at 734 Sequoia Drive, Crossville, Tennessee 38572.

9. Defendant Ameridose, LLC ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough,

Massachusetts 01581. Ameridose is owned by defendants Carla Conigliaro, Barry Cadden, Lisa Cadden, and Gregory Conigliaro. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President of MSM. Defendant, Barry Cadden, is the Treasurer of MSM. Defendant, Gregory Conigliaro is the Secretary of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director, Gregory Conigliaro is the Secretary and Director and Lisa Conigliaro Cadden is Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546,

Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden was a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden was the Treasurer and Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of Massachusetts. Mr. Conigliaro is the President and Director of MSM and MSMSW. Mr. Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 is a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and is a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC.

20. Defendant Specialty Surgery Center, PLLC ("Specialty Surgery Center") is a Professional Limited Liability Company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery Center's principal place of business is 116 Brown Avenue, Crossville, Tennessee 38555. Specialty Surgery Center's registered agent for service of process is Donathan M. Ivey, 116 Brown Avenue, Crossville, Tennessee 38555.

21. Defendant Kenneth R. Lister, M.D. ("Dr. Lister") is an individual residing at 8317 Neubert Springs Road, Knoxville, TN 37920 and is a citizen and resident of the State of Tennessee. During all relevant times, Kenneth Lister was an employee of Specialty Surgery Center. Kenneth Lister is a medical doctor and practices in the specialty of anesthesiology. Kenneth Lister was involved in the day to day operations at Specialty Surgery Center.

22. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the "NECC Related Defendants."

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.§ 1334(b) because as described herein each claim asserted herein is related to a case under Title 11 of the United States Bankruptcy Code (the "Bankruptcy Code"). Specifically, on December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code. This case is pending in the United States Bankruptcy Court for the District of Massachusetts and is styled as *In re: New England Compounding Pharmacy*, Case No. 12:12-19882 HJB (the "Bankruptcy Proceeding"). The Bankruptcy Court has appointed a bankruptcy trustee to administer the Bankruptcy Estate.

24. Further, as a result of the large number of actions arising from the NECC-related meningitis outbreak, On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multi district Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS (the "MDL Proceeding"). The MDL Proceeding has been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

25. The Bankruptcy Court has not yet set a deadline for filing of claims against NECC's estate. Plaintiff will submit a timely claim in the Bankruptcy Proceeding at the appropriate time.

26. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. On

information and belief, some if not all of the aforementioned individuals are insureds under NECC's insurance policies. All aforementioned individuals and entities are NECC Related Defendants as that term is used throughout this Complaint.

27. Adversarial cases seeking damages for the benefit of the Bankruptcy Estate and its unsecured creditors have been filed in the Bankruptcy Proceeding against each of the NECC Related Defendants.

28. On information and belief, Specialty Surgery Center will file a claim in the Bankruptcy Proceeding seeking contribution, indemnity, and/or breach of warranty damages from NECC Bankruptcy Estate and will seek relief from the automatic stay provided for in 11 U.S.C. § 362.

29. By Order dated May 31, 2013, Judge Saylor in the MDL Proceeding ruled that federal courts have subject matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC, whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the NECC Related Defendants. Accordingly, this action falls within the ruling of this May 31, 2013 Order, and this Court has subject matter jurisdiction over this action.

30. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against the Specialty Surgery Center and Dr. Lister pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

31. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part

of the events and actions giving rise to the matters asserted in the Complaint occurred in this jurisdiction.

32. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

33. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

34. The NECC Related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

Relevant background

35. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

36. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

37. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

38. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

39. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

40. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

41. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

42. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

43. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

44. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

45. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy

technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

46. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC.

47. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

48. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

49. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

50. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

51. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

52. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

Claims Against the NECC Related Defendants

53. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

54. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory

Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regard to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

55. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided the New England Compounding Center's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

56. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.

57. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

58. Eighty-three out of 321 observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All 50 out of 50 vials tested confirmed the presence of

live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least 40 fungal meningitis cases.

59. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least 53 instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

60. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

61. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (MPA) 80 mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

62. NECC identified Specialty Surgery Center in Crossville, Tennessee as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.

63. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

64. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

65. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

66. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

67. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

68. According to its internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

69. According to its internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding

pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

70. ARL also states on its internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

71. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. ***You should expect nothing less from the testing laboratory you entrust***." (emphasis in original)

72. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "**[t]esting methods and technologies [are] unparalleled in the market today[.]**" (emphasis in original)

73. With respect to its sterility tests, ARL, on its website, stated: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

74. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

75. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two

5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

76. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

77. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

78. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

79. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

80. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

81. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68

to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

82. ARL was aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

83. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

84. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

85. In 2007, Mr. Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

86. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

87. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Mr. Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Mr. Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

88. While the requirements of USP 71 were not relaxed for compounding pharmacies after Mr. Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

89. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

90. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

91. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Ensure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

92. GDC maintained a high degree of control over the premises leased by NECC.

93. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.

94. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

NECC and the risks of pharmacy compounding

95. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. In other words, the risks associated with compounded drugs have been known for years.

96. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that…follows appropriate measures to ensure that injectable products are free of contamination."

97. On March 24, 2005, *USA Today* published a front page article with the following headline: "**Safety concerns grow over pharmacy-mixed drugs.**" That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

98. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

99. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

100. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

101. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

102. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

The Fungal Meningitis Outbreak

103. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

104. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of ESIs at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health, contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

105. Dr. Kainer told personnel at St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received ESIs at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

106. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

107. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.

108. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

109. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

110. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be

very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

Judy Collins is injected with MPA from NECC and has symptoms of fungal meningitis

111. On September 12, 2012, Judy Collins received a lumbar epidural steroid injection ("ESI") at Specialty Surgery Center. During that procedure the anesthesiologist injected 80 mg/mL of MPA into Judy Collins's lower back.

112. Judy Collins's September 12, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

113. Judy Collins's September 12, 2012 injection of MPA caused her symptoms consistent with fungal meningitis.

114. On or around October 4, 2012 Judy Collins developed headache, nausea and vomiting.

115. On October 4, 2012 Judy Collins presented to the Cumberland Medical Center emergency room. On October 4, 2012, Judy Collins had a lumbar puncture and lumbar MRI. The lumbar MRI showed possible inflammation and possible epidural abscess.

116. Judy Collins continued having symptoms of consistent with meningitis, including a headache and ringing in her ears.

117. On October 28, 2012, Judy Collins returned to the emergency room at Cumberland Medical Center, where she received another lumbar puncture.

118. On November 6, 2012, Judy Collins returned to the emergency room at Cumberland Medical Center and received a lumber MRI.

119. On information and belief, the MPA injected into Judy Collins's lumbar spine came from one or more of the three recalled contaminated lots.

120. As a direct and proximate result of the contaminated ESIs, Judy Collins had symptoms consistent with meningitis, received two lumbar punctures and was subject to additional outpatient testing.

CAUSES OF ACTION

COUNT I
NEGLIGENCE
(Against NECC Related Defendants)

121. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

122. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC related Defendants owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Plaintiff Judy Collins.

123. Specifically, but without limitation:

a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Plaintiff a duty to properly conduct tests to ensure that the methylprednisolone acetate was safe and free of contamination.

124. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a

designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through its supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

125. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Plaintiff.

126. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

127. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Plaintiff's injuries.

128. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into her in September 2012.

129. As a direct and proximate result of the negligence of these Defendants, and being injected with contaminated doses of methylprednisolone acetate, Judy Collins has suffered injuries and damages, including but not limited to, pain and suffering, emotional distress,

anxiety, emotional damage and has incurred medical and other expenses. Such damages render her no longer able to engage in her daily activities and enjoyment of life.

COUNT II
NEGLIGENCE PER SE
(Against NECC Related Defendants)

130. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

131. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

132. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

133. Defendants also violated Massachusetts law and its pharmacy licensing obligations.

134. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Judy Collins has suffered injuries and damages as described with particularity, above.

COUNT III
NEGLIGENT SUPERVISION
(Against NECC Related Defendants)

135. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

136. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

137. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

138. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

139. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff, Judy Collins.

140. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Judy Collins has suffered injuries and damages as described with particularity, above.

COUNT IV
PUBLIC NUISANCE
(Against Barry Cadden, Gregory Conigliaro and GDC)

141. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

142. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

143. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

144. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

145. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

146. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

147. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

148. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Plaintiff's injuries.

149. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Judy Collins special injury in that Judy Collins has sustained injuries to her personal health.

150. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Judy Collins has suffered injuries and damages as described with particularity, above.

COUNT V
DECEPTIVE TRADE PRACTICES ACT
(Against NECC Related Defendants)

151. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

152. The NECC Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

153. The NECC Related Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act. The NECC Related Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

154. As described herein, the NECC Related Defendants represented that their product had characteristics, uses and benefits that it did not have.

155. As described herein, the NECC Related Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

156. The NECC Related Defendants failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use NECC Related Defendants' product.

157. The NECC Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Plaintiff, constituting a violation of the Act.

158. The NECC Related Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

159. The NECC Related Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

160. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

161. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiff.

162. The NECC Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the product;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

163. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally, the NECC Related

Defendants were unethical and unscrupulous, and caused substantial injury to consumers. The NECC Related Defendants engaged in unconscionable actions and course of action.

164. The NECC Related Defendants willfully engaged in the conduct described herein, which they knew were deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

165. The NECC Related Defendants are liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

COUNT VI
PRODUCT LIABILITY CLAIMS
(Against Specialty Surgery Center and Dr. Kenneth Lister)

166. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

167. The MPA injected into Judy Collins's lumbar spine on September 12, 2012 was compounded by NECC.

168. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (Eastern Division) No. 12-19882-HJB.

169. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

170. Plaintiff could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

171. Plaintiff's claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

172. NECC has ceased operations.

173. NECC is unable to pay its debts as they fall due.

174. NECC is unable to pay its debts in the ordinary course of its business.

175. NECC's liabilities exceed its assets.

176. NECC is insolvent as declared by order dated July 24, 2013 in the Bankruptcy Proceeding.

177. Specialty Surgery Center procured the MPA injected into Judy Collins's lumbar spine from NECC.

178. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery Center injected it into Judy Collins's lumbar spine on September 12, 2012.

179. Specialty Surgery Center charged Judy Collins for ESIs administered to Judy Collins.

180. Specialty Surgery Center acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Judy Collins.

181. Specialty Surgery Center was engaged in the business of selling MPA compounded by NECC.

182. Accordingly, Specialty Surgery Center is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

183. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiff Judy Collins to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA

injected into Judy Collins's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.

184. The MPA that Specialty Surgery Center injected into Judy Collins's lumbar spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

185. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

186. The MPA sold and distributed by Specialty Surgery Center was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery Center breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

187. Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Judy Collins's lumbar spine.

188. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act, T.C.A. § 29-26-101, *et. seq*. Plaintiff has served notice letters as required by the TMMA, but sixty days haven not yet passed since service of those letters. Plaintiff files this action to preserve her products liability action, and will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

DAMAGES

189. As a direct and proximate result of the Defendants' wrongful conduct as described above, Judy Collins has suffered physical injuries, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.

190. The long term effects of Judy Collins's illness is unknown.

191. Judy Collins has incurred and continues to incur medical and other expenses.

PUNITIVE DAMAGES

192. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiff therefore is entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

193. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiff's non-economic damages are purportedly capped at $750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.

194. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiff's constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall

be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever . . . and shall forever remain inviolate." Therefore, Judy Collins requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

195. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiff is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Judy Collins requests the following relief:

A. A judgment to Plaintiff for compensatory damages;

B. A judgment for punitive damages in an amount to be determined by the trier of fact;

C. A jury to determine all disputed factual issues;

D. For costs of this cause and reasonable attorneys' fees; and

E. For such further relief as the Court may deem just and proper.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEAST DIVISION

DANETTE GRAHAM, Plaintiff, v. AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SPECIALTY SURGERY CENTER, PLLC, DR. KENNETH R. LISTER, Defendants.	)	Case No. JURY DEMAND

COMPLAINT

The Plaintiff, Danette Graham, for her cause of action against the defendants respectfully states to the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of the widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 200 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as

"MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff Danette Graham and for many others who have suffered serious and at times catastrophic injuries.

4. During the period June through August 2012, Specialty Surgery Center, PLLC ("Specialty Surgery Center") purchased approximately 220 vials of MPA from NECC and then sold and administered the MPA to patients including Danette Graham.

5. On August 29, 2012, Danette Graham received a lumbar epidural steroid injection ("ESI") at Specialty Surgery Center. During that procedure the anesthesiologist injected 80 mg/mL of MPA into Danette Graham's lower back.

6. On information and belief, Danette Graham's August 29, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

7. Danette Graham's August 29, 2012 injection of MPA caused her to undergo treatment for symptoms consistent with fungal meningitis.

PARTIES

8. Plaintiff Danette Graham is a citizen and resident of Tennessee and resides at 28 Heather Glen Drive, Crossville, Tennessee 38558.

9. Defendant Ameridose, LLC ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581. Ameridose is owned by defendants Carla Conigliaro, Barry Cadden, Lisa Cadden, and Gregory

Conigliaro. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President of MSM. Defendant, Barry Cadden, is the Treasurer of MSM. Defendant, Gregory Conigliaro is the Secretary of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director, Gregory Conigliaro is the Secretary and Director and Lisa Conigliaro Cadden is Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden was a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden was the Treasurer and Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of

Massachusetts. Mr. Conigliaro is the President and Director of MSM and MSMSW. Mr. Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 is a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and is a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC.

20. Defendant Specialty Surgery Center, PLLC ("Specialty Surgery Center") is a Professional Limited Liability Company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery Center's principal place of business is 116 Brown Avenue, Crossville, Tennessee 38555. Specialty Surgery Center's registered agent for service of process is Donathan M. Ivey, 116 Brown Avenue, Crossville, Tennessee 38555.

21. Defendant Kenneth R. Lister, M.D. ("Dr. Lister") is an individual residing at 8317 Neubert Springs Road, Knoxville, TN 37920 and is a citizen and resident of the State of Tennessee. During all relevant times, Kenneth Lister was an employee of Specialty Surgery Center. Kenneth Lister is a medical doctor and practices in the specialty of anesthesiology. Kenneth Lister was involved in the day to day operations at Specialty Surgery Center.

22. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the "NECC Related Defendants."

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.§ 1334(b) because as described herein each claim asserted herein is related to a case under Title 11

of the United States Bankruptcy Code (the "Bankruptcy Code"). Specifically, on December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code. This case is pending in the United States Bankruptcy Court for the District of Massachusetts and is styled as *In re: New England Compounding Pharmacy*, Case No. 12:12-19882 HJB (the "Bankruptcy Proceeding"). The Bankruptcy Court has appointed a bankruptcy trustee to administer the Bankruptcy Estate.

24. Further, as a result of the large number of actions arising from the NECC-related meningitis outbreak, On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multi district Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS (the "MDL Proceeding"). The MDL Proceeding has been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

25. The Bankruptcy Court has not yet set a deadline for filing of claims against NECC's estate. Plaintiff will submit a timely claim in the Bankruptcy Proceeding at the appropriate time.

26. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. On information and belief, some if not all of the aforementioned individuals are insureds under

NECC's insurance policies. All aforementioned individuals and entities are NECC Related Defendants as that term is used throughout this Complaint.

27. Adversarial cases seeking damages for the benefit of the Bankruptcy Estate and its unsecured creditors have been filed in the Bankruptcy Proceeding against each of the NECC Related Defendants.

28. On information and belief, Specialty Surgery Center will file a claim in the Bankruptcy Proceeding seeking contribution, indemnity, and/or breach of warranty damages from the Bankruptcy Estate and will seek relief from the automatic stay provided for in 11 U.S.C. § 362.

29. By Order dated May 31, 2013, Judge Saylor in the MDL Proceeding ruled that federal courts have subject matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC, whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the NECC Related Defendants. Accordingly, this action falls within the ruling of this May 31, 2013 Order, and this Court has subject matter jurisdiction over this action.

30. In addition, or in the alternative to the bases for jurisdiction already asserted, this Court has subject matter jurisdiction over all claims against Specialty Surgery Center and Dr. Lister pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

31. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the

events and actions giving rise to the matters asserted in the Complaint occurred in this jurisdiction.

32. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

33. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

34. The NECC Related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

Relevant Background

35. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

36. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

37. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

38. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

39. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

40. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

41. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

42. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

43. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

44. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

45. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians

employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

46. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC.

47. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

48. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

49. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

50. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

51. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

52. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

Claims Against the NECC Related Defendants

53. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

54. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa

Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regard to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

55. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided the New England Compounding Center's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

56. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.

57. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

58. Eighty-three out of 321 observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All 50 out of 50 vials tested confirmed the presence of live microbes

(whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least 40 fungal meningitis cases.

59. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least 53 instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

60. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

61. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (MPA) 80 mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

62. NECC identified Specialty Surgery Center in Crossville, Tennessee as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.

63. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

64. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

65. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

66. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

67. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

68. According to its Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

69. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding

pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

70. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

71. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. ***You should expect nothing less from the testing laboratory you entrust***." (emphasis in original)

72. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "**[t]esting methods and technologies [are] unparalleled in the market today[.]**" (emphasis in original)

73. With respect to its sterility tests, ARL, on its website, stated: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

74. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

75. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml

vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

76. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

77. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

78. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

79. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

80. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

81. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68

to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

82. ARL was aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

83. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

84. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

85. In 2007, Mr. Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

86. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

87. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Mr. Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Mr. Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

88. While the requirements of USP 71 were not relaxed for compounding pharmacies after Mr. Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

89. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

90. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

91. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Ensure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

92. GDC maintained a high degree of control over the premises leased by NECC.

93. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.

94. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

NECC and the Risks of Pharmacy Compounding

95. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. In other words, the risks associated with compounded drugs have been known for years.

96. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that…follows appropriate measures to ensure that injectable products are free of contamination."

97. On March 24, 2005, *USA Today* published a front page article with the following headline: "**Safety concerns grow over pharmacy-mixed drugs.**" That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

98. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

99. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

100. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

101. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

102. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

The Fungal Meningitis Outbreak

103. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

104. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of ESIs at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health, contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

105. Dr. Kainer told personnel at St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received ESIs at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

106. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

107. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.

108. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

109. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

110. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of

the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might have just one or two of these symptoms.

Danette Graham is Injected with MPA from NECC and is Treated for Fungal Meningitis

111. On August 29, 2012, Danette Graham received a lumbar ESI at Specialty Surgery Center. During that procedure the anesthesiologist injected 80mg. of 80 mg/mL of MPA into Danette Graham's lower back.

112. On information and belief, Danette Graham's August 29, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

113. Danette Graham's August 29, 2012 injection of MPA caused her symptoms consistent with fungal meningitis.

114. On or around October 17, 2012 Danette Graham developed headache, nausea and neck pain.

115. On October 17, 2012 Danette Graham presented to the Cumberland Medical Center emergency room. On October 18, 2012, Danette Graham had a lumbar puncture and was treated with anti-fungal medication as a precaution.

116. Danette Graham was discharged from the hospital on October 18, 2012 after her lumbar puncture returned normal results.

117. On November 17, 2012, Danette Graham presented to Satellite Medical Center after falling as a side effect of her medications. Danette Graham fell and injured the right side of her face, right shoulder, and right ribs on or around November 12, 2012.

118. On information and belief, The MPA injected into Danette Graham's lumbar spine came from one or more of the three recalled contaminated lots.

119. As a direct and proximate result of the contaminated ESIs, Danette Graham received a lumbar puncture and received additional injuries after falling due to her medications.

CAUSES OF ACTION

COUNT I
NEGLIGENCE
(Against NECC Related Defendants)

120. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

121. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC related Defendants owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Plaintiff Danette Graham.

122. Specifically, but without limitation:

a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Plaintiff a duty to properly conduct tests to ensure that the methylprednisolone acetate was safe and free of contamination.

123. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and

agents, engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

124. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Plaintiff.

125. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

126. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Plaintiff's injuries.

127. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into her in August 2012.

128. As a direct and proximate result of the negligence of these Defendants, and being injected with contaminated doses of methylprednisolone acetate, Danette Graham has suffered injuries and damages including, but not limited to, pain and suffering, emotional distress, anxiety, emotional damage, and has incurred medical and other expenses. Such damages render her no longer able to engage in her daily activities and enjoyment of life.

COUNT II
NEGLIGENCE PER SE
(Against NECC Related Defendants)

129. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

130. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

131. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

132. Defendants also violated Massachusetts law and its pharmacy licensing obligations.

133. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Danette Graham has suffered injuries and damages as described with particularity, above.

COUNT III
NEGLIGENT SUPERVISION
(Against NECC Related Defendants)

134. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

135. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to

investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

136. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

137. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

138. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff, Danette Graham.

139. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Danette Graham has suffered injuries and damages as described with particularity, above.

COUNT IV
PUBLIC NUISANCE
(Against Barry Cadden, Gregory Conigliaro and GDC)

140. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

141. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

142. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

143. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

144. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

145. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

146. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

147. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Plaintiff's injuries.

148. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Danette Graham special injury in that Danette Graham has sustained injuries to her personal health.

149. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Danette Graham has suffered injuries and damages as described with particularity, above.

COUNT V
DECEPTIVE TRADE PRACTICES ACT
(Against NECC Related Defendants)

150. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

151. The NECC Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

152. The NECC Related Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act. The NECC Related Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

153. As described herein, the NECC Related Defendants represented that their product had characteristics, uses and benefits that it did not have.

154. As described herein, the NECC Related Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

155. The NECC Related Defendants failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use NECC Related Defendants' product.

156. The NECC Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Plaintiff, constituting a violation of the Act.

157. The NECC Related Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

158. The NECC Related Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

159. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

160. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiff.

161. The NECC Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the product;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

162. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally, the NECC Related Defendants were unethical and unscrupulous, and caused substantial injury to consumers. The NECC Related Defendants engaged in unconscionable actions and course of action.

163. The NECC Related Defendants willfully engaged in the conduct described herein, which they knew was deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

164. The NECC Related Defendants are liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

COUNT VI
PRODUCT LIABILITY CLAIMS
(Against Specialty Surgery Center and Dr. Kenneth Lister)

165. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

166. The MPA injected into Danette Graham's lumbar spine on August 29, 2012 was compounded by NECC.

167. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (Eastern Division) No. 12-19882-HJB.

168. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

169. Plaintiff could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

170. Plaintiff's claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

171. NECC has ceased operations.

172. NECC is unable to pay its debts as they fall due.

173. NECC is unable to pay its debts in the ordinary course of its business.

174. NECC's liabilities exceed its assets.

175. NECC is insolvent as declared by order dated July 24, 2013 in the Bankruptcy Proceeding.

176. Specialty Surgery Center procured the MPA injected into Danette Graham's lumbar spine from NECC.

177. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery Center injected it into Danette Graham's lumbar spine on August 29, 2012.

178. Specialty Surgery Center charged Danette Graham for ESIs administered to Danette Graham.

179. Specialty Surgery Center acted as a seller or distributor of MPA compounded by NECC when it sold and administered ESIs to patients, including Danette Graham.

180. Specialty Surgery Center was engaged in the business of selling MPA compounded by NECC.

181. Accordingly, Specialty Surgery Center is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

182. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiff Danette Graham to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA injected into Danette Graham's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.

183. The MPA that Specialty Surgery Center injected into Danette Graham's lumbar spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

184. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

185. The MPA sold and distributed by Specialty Surgery Center was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery Center breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

186. Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Danette Graham's lumbar spine.

187. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act, T.C.A. § 29-26-101, *et. seq*. Plaintiff has served notice letters as required by the TMMA, but sixty days haven not yet passed since service of those letters. Plaintiff files this action to preserve her products liability action, and will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

DAMAGES

188. As a direct and proximate result of the Defendants' wrongful conduct as described above, Danette Graham has suffered physical injuries, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.

189. The long term effects of Danette Graham's illness are unknown.

190. Danette Graham has incurred and continues to incur medical and other expenses.

PUNITIVE DAMAGES

191. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiff therefore is entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

192. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiff's non-economic damages are purportedly capped at $750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.

193. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiff's constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense

whatever...and shall forever remain inviolate." Therefore, Danette Graham requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

194. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiff is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Danette Graham requests the following relief:

A. A judgment to plaintiff for compensatory damages in excess of $75,000;

B. A judgment for punitive damages in an amount to be determined by the trier of fact;

C. A jury to determine all disputed factual issues;

D. For costs of this cause and reasonable attorneys' fees; and

E. For such further relief as the Court may deem just and proper.

Respectfully submitted,

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Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEAST DIVISION

SHIRLEY SAVERCOOL, Plaintiff, v. AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SPECIALTY SURGERY CENTER, PLLC, DR. KENNETH R. LISTER, Defendants.	)	Case No. JURY DEMAND

COMPLAINT

The Plaintiff, Shirley Savercool, for her cause of action against the defendants respectfully states to the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of the widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 200 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as

"MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff Shirley Savercool and for many others who have suffered serious and at times catastrophic injuries.

4. During the period June through August 2012, Specialty Surgery Center, PLLC ("Specialty Surgery Center") purchased approximately 220 vials of MPA from NECC and then sold and administered the MPA to patients including Shirley Savercool.

5. On September 13, 2012, Shirley Savercool received a lumbar epidural steroid injection ("ESI") at Specialty Surgery Center. During that procedure the anesthesiologist injected 20mg. of 80 mg/mL of MPA into Shirley Savercool's lower back.

6. On information and belief, Shirley Savercool's September 13, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

7. Shirley Savercool's September 13, 2012 injection of MPA caused her fungal meningitis.

PARTIES

8. Plaintiff Shirley Savercool is a citizen and resident of Tennessee and resides at 104 Forest Hill Drive, Crossville, Tennessee, 38558.

9. Defendant Ameridose, LLC ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581. Ameridose is owned by defendants Carla Conigliaro, Barry Cadden, Lisa Cadden, and Gregory

Conigliaro. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President of MSM. Defendant, Barry Cadden, is the Treasurer of MSM. Defendant, Gregory Conigliaro is the Secretary of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director, Gregory Conigliaro is the Secretary and Director and Lisa Conigliaro Cadden is Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden was a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden was the Treasurer and Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of

Massachusetts. Mr. Conigliaro is the President and Director of MSM and MSMSW. Mr. Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 is a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and is a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC.

20. Defendant Specialty Surgery Center, PLLC ("Specialty Surgery Center") is a Professional Limited Liability Company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery Center's principal place of business is 116 Brown Avenue, Crossville, Tennessee 38555. Specialty Surgery Center's registered agent for service of process is Donathan M. Ivey, 116 Brown Avenue, Crossville, Tennessee 38555.

21. Defendant Kenneth R. Lister, M.D. ("Dr. Lister") is an individual residing at 8317 Neubert Springs Road, Knoxville, TN 37920 and is a citizen and resident of the State of Tennessee. During all relevant times, Kenneth Lister was an employee of Specialty Surgery Center. Kenneth Lister is a medical doctor and practices in the specialty of anesthesiology. Kenneth Lister was involved in the day to day operations at Specialty Surgery Center.

22. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the "NECC Related Defendants."

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.§ 1334(b) because as described herein each claim asserted herein is related to a case under Title 11

of the United States Bankruptcy Code (the "Bankruptcy Code"). Specifically, on December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code. This case is pending in the United States Bankruptcy Court for the District of Massachusetts and is styled as *In re: New England Compounding Pharmacy*, Case No. 12:12-19882 HJB (the "Bankruptcy Proceeding"). The Bankruptcy Court has appointed a bankruptcy trustee to administer the Bankruptcy Estate.

24. Further, as a result of the large number of actions arising from the NECC-related meningitis outbreak, On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multi district Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS (the "MDL Proceeding"). The MDL Proceeding has been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

25. The Bankruptcy Court has not yet set a deadline for filing of claims against NECC's estate. Plaintiff will submit a timely claim in the Bankruptcy Proceeding at the appropriate time.

26. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. On information and belief, some if not all of the aforementioned individuals are insureds under

NECC's insurance policies. All aforementioned individuals and entities are NECC Related Defendants as that term is used throughout this Complaint.

27. Adversarial cases seeking damages for the benefit of the Bankruptcy Estate and its unsecured creditors have been filed in the Bankruptcy Proceeding against each of the NECC Related Defendants.

28. On information and belief, Specialty Surgery Center will file a claim in the Bankruptcy Proceeding seeking contribution, indemnity, and/or breach of warranty damages from NECC Bankruptcy Estate and will seek relief from the automatic stay provided for in 11 U.S.C. § 362.

29. By Order dated May 31, 2013, Judge Saylor in the MDL Proceeding ruled that federal courts have subject matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC, whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the NECC Related Defendants. Accordingly, this action falls within the ruling of this May 31, 2013 Order, and this Court has subject matter jurisdiction over this action.

30. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject matter jurisdiction over all claims against Specialty Surgery Center and Dr. Lister pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

31. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the

events and actions giving rise to the matters asserted in the Complaint occurred in this jurisdiction.

32. At all times relevant the NECC Related Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

33. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

34. The NECC Related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

Relevant Background

35. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

36. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

37. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

38. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

39. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

40. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

41. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

42. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

43. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

44. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

45. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians

employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

46. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC.

47. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

48. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

49. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

50. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

51. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

52. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

Claims Against the NECC Related Defendants

53. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

54. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa

Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regard to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

55. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided the New England Compounding Center's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

56. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.

57. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

58. Eighty-three out of 321 observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All 50 out of 50 vials tested confirmed the presence of live microbes

(whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least 40 fungal meningitis cases.

59. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least 53 instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

60. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

61. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (MPA) 80 mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

62. NECC identified Specialty Surgery Center in Crossville, Tennessee as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.

63. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

64. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

65. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

66. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

67. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

68. According to its Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

69. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding

pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

70. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

71. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. You should expect nothing less from the testing laboratory you entrust." (emphasis in original)

72. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "[t]esting methods and technologies [are] unparalleled in the market today[.]" (emphasis in original)

73. With respect to its sterility tests, ARL, on its website, stated: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

74. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

75. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml

vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

76. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

77. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

78. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

79. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

80. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

81. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68

to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

82. ARL was aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

83. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

84. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

85. In 2007, Mr. Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

86. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

87. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Mr. Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Mr. Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

88. While the requirements of USP 71 were not relaxed for compounding pharmacies after Mr. Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

89. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

90. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

91. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Ensure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

92. GDC maintained a high degree of control over the premises leased by NECC.

93. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.

94. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

NECC and the Risks of Pharmacy Compounding

95. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. In other words, the risks associated with compounded drugs have been known for years.

96. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that…follows appropriate measures to ensure that injectable products are free of contamination."

97. On March 24, 2005, USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

98. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

99. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

100. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

101. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

102. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

The Fungal Meningitis Outbreak

103. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

104. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of ESIs at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health, contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

105. Dr. Kainer told personnel at St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received ESIs at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

106. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

107. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.

108. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

109. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

110. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of

the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might have just one or two of these symptoms.

Shirley Savercool is Injected with MPA from NECC and Develops Fungal Meningitis

111. On September 13, 2012, Shirley Savercool received a lumbar ESI at Specialty Surgery Center. During that procedure the anesthesiologist injected 40mg. of 80 mg/mL of MPA into Shirley Savercool's lower back.

112. Shirley Savercool's September 13, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

113. Shirley Savercool's September 13, 2012 injection of MPA caused her fungal meningitis.

114. On or around September 20, 2012 Shirley Savercool developed pain in the lower back, low-grade fever and left foot weakness.

115. On October 3, 2012 Shirley Savercool presented to the Cumberland Medical Center emergency room. Shirley Savercool had a brain MRI and a lumbar spine MRI which both came back negative and the patient was sent home.

116. Shirley Savercool continued to have symptoms and returned to the Cumberland Medical Center emergency room on October 5, 2013. A lumbar puncture was performed and a CSF analysis was suggestive of meningitis.

117. Shirley Savercool was diagnosed with fungal meningitis and admitted to Cumberland Medical Center on October 6, 2013 where she was treated with anti-fungal medication. Shirley Savercool remained a patient at Cumberland Medical Center until October 22, 2012.

118. The MPA injected into Shirley Savercool's lumbar spine came from one or more of the three recalled contaminated lots.

119. As a direct and proximate result of the contaminated ESIs, Shirley Savercool contracted fungal meningitis, became very ill and continues to suffer from the effects of fungal meningitis.

CAUSES OF ACTION

COUNT I
NEGLIGENCE
(Against NECC Related Defendants)

120. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

121. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC related Defendants owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Plaintiff Shirley Savercool.

122. Specifically, but without limitation:

a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Plaintiff a duty to properly conduct tests to ensure that the methylprednisolone acetate was safe and free of contamination.

123. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder,

tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents, engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

124. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Plaintiff.

125. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

126. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Plaintiff's injuries.

127. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into her in September 2012.

128. As a direct and proximate result of the negligence of these Defendants, and being injected with contaminated doses of methylprednisolone acetate, Shirley Savercool has suffered injuries and damages, including but not limited, to pain and suffering, emotional distress,

anxiety, emotional damage, and has incurred medical and other expenses. Such damages render her no longer able to engage in her daily activities and enjoyment of life.

COUNT II
NEGLIGENCE PER SE
(Against NECC Related Defendants)

129. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

130. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

131. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

132. Defendants also violated Massachusetts law and its pharmacy licensing obligations.

133. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Shirley Savercool has suffered injuries and damages as described with particularity, above.

WHEREFORE, the Plaintiff demands judgment against Defendants, jointly and severally, in an amount that will justly compensate her for their damages and future losses, together with interest, costs and their attorneys' fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT III
NEGLIGENT SUPERVISION
(Against NECC Related Defendants)

134. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

135. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

136. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

137. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

138. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff, Shirley Savercool.

139. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Shirley Savercool has suffered injuries and damages as described with particularity, above.

WHEREFORE, the Plaintiff demands judgment against the Defendants, jointly and severally, in an amount that will justly compensate her for her damages and future losses, together with interest, costs and attorneys' fees incurred in this action.

COUNT IV
PUBLIC NUISANCE
(Against Barry Cadden, Gregory Conigliaro and GDC)

140. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

141. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

142. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

143. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

144. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

145. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

146. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

147. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Plaintiff's injuries.

148. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Shirley Savercool special injury in that Shirley Savercool has sustained injuries to her personal health.

149. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Shirley Savercool has suffered injuries and damages as described with particularity, above.

COUNT V
DECEPTIVE TRADE PRACTICES ACT
(Against NECC Related Defendants)

150. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

151. The NECC Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

152. The NECC Related Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act. The NECC Related Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

153. As described herein, the NECC Related Defendants represented that their product had characteristics, uses and benefits that it did not have.

154. As described herein, the NECC Related Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

155. The NECC Related Defendants failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use NECC Related Defendants' product.

156. The NECC Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Plaintiff, constituting a violation of the Act.

157. The NECC Related Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

158. The NECC Related Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

159. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

160. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiff.

161. The NECC Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the product;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

162. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally, the NECC Related Defendants were unethical and unscrupulous, and caused substantial injury to consumers. The NECC Related Defendants engaged in unconscionable actions and course of action.

163. The NECC Related Defendants willfully engaged in the conduct described herein, which they knew was deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

164. The NECC Related Defendants are liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

COUNT VI
PRODUCT LIABILITY CLAIMS
(Against Specialty Surgery Center and Dr. Kenneth Lister)

165. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

166. The MPA injected into Shirley Savercool's lumbar spine on September 13, 2012 was compounded by NECC.

167. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (Eastern Division) No. 12-19882-HJB.

168. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

169. Plaintiff could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

170. Plaintiff's claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

171. NECC has ceased operations.

172. NECC is unable to pay its debts as they fall due.

173. NECC is unable to pay its debts in the ordinary course of its business.

174. NECC's liabilities exceed its assets.

175. NECC is insolvent as declared by order dated July 24, 2013 in the Bankruptcy Proceeding.

176. Specialty Surgery Center procured the MPA injected into Shirley Savercool's lumbar spine from NECC.

177. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery Center injected it into Shirley Savercool's lumbar spine on September 13, 2012.

178. Specialty Surgery Center charged Shirley Savercool for ESIs administered to Shirley Savercool.

179. Specialty Surgery Center acted as a seller or distributor of MPA compounded by NECC when it sold and administered ESIs to patients, including Shirley Savercool.

180. Specialty Surgery Center was engaged in the business of selling MPA compounded by NECC.

181. Accordingly, Specialty Surgery Center is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

182. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiff Shirley Savercool to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA injected into Shirley Savercool's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.

183. The MPA that Specialty Surgery Center injected into Shirley Savercool's lumbar spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

184. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

185. The MPA sold and distributed by Specialty Surgery Center was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery Center breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

186. Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Shirley Savercool's lumbar spine.

187. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act (the "TMMA"), T.C.A. § 29-26-101, *et. seq*. Plaintiff has served notice letters as required by the TMMA, but sixty days haven not yet passed since service of those letters. Plaintiff files this action to preserve her products liability action, and will amend

this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

DAMAGES

188. As a direct and proximate result of the Defendants' wrongful conduct as described above, Shirley Savercool has suffered physical injuries, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.

189. The long term effects of Shirley Savercool's illness are unknown.

190. Shirley Savercool remains under the care of physicians. Shirley Savercool has incurred and continues to incur medical and other expenses.

PUNITIVE DAMAGES

191. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiff therefore is entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

192. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiff's non-economic damages are purportedly capped at $750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.

193. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiff's constitutionally protected right to trial by jury. Those

provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever...and shall forever remain inviolate." Therefore, Shirley Savercool requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

194. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiff is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Shirley Savercool requests the following relief:

A. A judgment to plaintiff for compensatory damages in excess of $75,000;

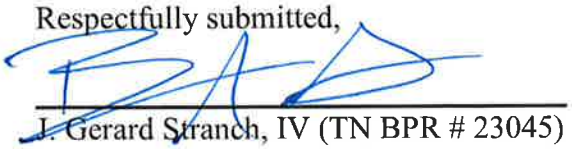
B. A judgment for punitive damages in an amount to be determined by the trier of fact;

C. A jury to determine all disputed factual issues;

D. For costs of this cause and reasonable attorneys' fees; and

E. For such further relief as the Court may deem just and proper.

Respectfully submitted,



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IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEAST DIVISION

DALE WILLIS, Plaintiff, v. AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SPECIALTY SURGERY CENTER, PLLC, DR. KENNETH R. LISTER, Defendants.	)	Case No. JURY DEMAND

COMPLAINT

The Plaintiff, Dale Willis, for his cause of action against the defendants respectfully states to the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of the widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 200 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as "MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff Dale Willis and for many others who have suffered serious and at times catastrophic injuries.

4. During the period June through August 2012, Specialty Surgery Center, PLLC ("Specialty Surgery Center") purchased approximately 220 vials of MPA from NECC and then sold and administered the MPA to patients including Dale Willis.

5. On July 17, 2012, Dale Willis received a lumbar epidural steroid injection ("ESI") at Specialty Surgery Center. During that procedure the anesthesiologist injected 20mg. of 80 mg/mL of MPA into Dale Willis's lower back.

6. On information and belief, Dale Willis's July 17, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

7. Dale Willis's July 17, 2012 injection of MPA caused him to undergo treatment for symptoms consistent with fungal meningitis.

PARTIES

8. Plaintiff Dale Willis is a citizen and resident of Tennessee and resides at 7308 Kanapolis Drive, Crossville, TN 38570.

9. Defendant Ameridose, LLC ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581. Ameridose is owned by defendants Carla Conigliaro, Barry Cadden, Lisa Cadden, and Gregory Conigliaro. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President of MSM. Defendant, Barry Cadden, is the Treasurer of MSM. Defendant, Gregory Conigliaro is the Secretary of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director, Gregory Conigliaro is the Secretary and Director and Lisa Conigliaro Cadden is Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden was a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden was the Treasurer and Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the

Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of Massachusetts. Mr. Conigliaro is the President and Director of MSM and MSMSW. Mr. Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 is a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and is a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC.

20. Defendant Specialty Surgery Center, PLLC ("Specialty Surgery Center") is a Professional Limited Liability Company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery Center's principal place of business is 116 Brown Avenue, Crossville, Tennessee 38555. Specialty Surgery Center's registered agent for service of process is Donathan M. Ivey, 116 Brown Avenue, Crossville, Tennessee 38555.

21. Defendant Kenneth R. Lister, M.D. ("Dr. Lister") is an individual residing at 8317 Neubert Springs Road, Knoxville, TN 37920 and is a citizen and resident of the State of Tennessee. During all relevant times, Kenneth Lister was an employee of Specialty Surgery

Center. Kenneth Lister is a medical doctor and practices in the specialty of anesthesiology. Kenneth Lister was involved in the day to day operations at Specialty Surgery Center.

22. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the "NECC Related Defendants."

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.§ 1334(b) because as described herein each claim asserted herein is related to a case under Title 11 of the United States Bankruptcy Code (the "Bankruptcy Code"). Specifically, on December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code. This case is pending in the United States Bankruptcy Court for the District of Massachusetts and is styled as *In re: New England Compounding Pharmacy*, Case No. 12:12-19882 HJB (the "Bankruptcy Proceeding"). The Bankruptcy Court has appointed a bankruptcy trustee to administer the Bankruptcy Estate.

24. Further, as a result of the large number of actions arising from the NECC-related meningitis outbreak, On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multi district Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS (the "MDL Proceeding"). The MDL Proceeding has been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

25. The Bankruptcy Court has not yet set a deadline for filing of claims against NECC's estate. Plaintiff will submit a timely claim in the Bankruptcy Proceeding at the appropriate time.

26. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. On information and belief, some if not all of the aforementioned individuals are insureds under NECC's insurance policies. All aforementioned individuals and entities are NECC Related Defendants as that term is used throughout this Complaint.

27. Adversarial cases seeking damages for the benefit of the Bankruptcy Estate and its unsecured creditors have been filed in the Bankruptcy Proceeding against each of the NECC Related Defendants.

28. On information and belief, Specialty Surgery Center will file a claim in the Bankruptcy Proceeding seeking contribution, indemnity, and/or breach of warranty damages from NECC Bankruptcy Estate and will seek relief from the automatic stay provided for in 11 U.S.C. § 362.

29. By Order dated May 31, 2013, Judge Saylor in the MDL Proceeding ruled that federal courts have subject matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC, whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the NECC Related Defendants. Accordingly, this action falls within the ruling of this May 31, 2013 Order and this Court has subject matter jurisdiction over this action.

30. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject matter jurisdiction over all claims against the Surgery Specialty Center and

Dr. Lister pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

31. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in this jurisdiction.

32. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

33. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

34. The NECC Related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

Relevant background

35. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

36. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

37. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

38. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

39. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

40. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

41. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

42. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

43. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

44. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

45. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

46. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC.

47. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

48. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

49. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the

"Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

50. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

51. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

52. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

Claims Against the NECC Related Defendants

53. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

54. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have

known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regard to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

55. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided the New England Compounding Center's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

56. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.

57. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

58. Eighty-three out of 321 observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All 50 out of 50 vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least 40 fungal meningitis cases.

59. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least 53 instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

60. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

61. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (MPA) 80 mg/ml that it had compounded and sold:

Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

62. NECC identified Specialty Surgery Center in Crossville, Tennessee as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.

63. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

64. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

65. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

66. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

67. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy

mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

68. According to its internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

69. According to its internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

70. ARL also states on its internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

71. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. ***You should expect nothing less from the testing laboratory you entrust***." (emphasis in original)

72. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "**[t]esting methods and technologies [are] unparalleled in the market today[.]**" (emphasis in original)

73. With respect to its sterility tests, ARL, on its website, stated: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence

of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

74. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

75. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

76. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

77. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

78. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

79. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

80. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

81. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

82. ARL was aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

83. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

84. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

85. In 2007, Mr. Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

86. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse

events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

87. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Mr. Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Mr. Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

88. While the requirements of USP 71 were not relaxed for compounding pharmacies after Mr. Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

89. GDC, which is an acronym for "Gregory D. Conigliaro", owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

90. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

91. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Ensure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

92. GDC maintained a high degree of control over the premises leased by NECC.

93. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.

94. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

NECC and the risks of pharmacy compounding

95. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. In other words, the risks associated with compounded drugs have been known for years.

96. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that…follows appropriate measures to ensure that injectable products are free of contamination."

97. On March 24, 2005, *USA Today* published a front page article with the following headline: "**Safety concerns grow over pharmacy-mixed drugs.**" That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

98. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

99. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

100. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

101. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

102. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that

"contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

The Fungal Meningitis Outbreak

103. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

104. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of ESIs at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health, contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

105. Dr. Kainer told personnel at St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received ESI's at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

106. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

107. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.

108. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

109. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

110. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

Dale Willis is injected with MPA from NECC and develops fungal meningitis

111. On July 17, 2012 Dale Willis received a lumbar ESI at Specialty Surgery Center. During that procedure the anesthesiologist injected 80 mg/mL of MPA into Dale Willis's lower back.

112. On information and belief, Dale Willis's July 17, 2012 injection came from a contaminated lot of MPA that was purchased from NECC. The contaminated lot was subsequently recalled by NECC.

113. Dale Willis's July 17, 2012 injection of MPA caused him symptoms consistent with fungal meningitis.

114. On October 10, 2012 Dale Willis presented to the Cookeville Regional Medical Center emergency room with a headache. Dale Willis had a spinal tap which came back negative.

115. On information and belief, the MPA injected into Dale Willis's lumbar spine came from one or more of the three recalled contaminated lots.

116. As a direct and proximate result of the contaminated ESI, Dale Willis suffered symptoms of fungal meningitis and had to endure a lumbar puncture to test for meningitis.

CAUSES OF ACTION

COUNT I
NEGLIGENCE
(Against NECC Related Defendants)

117. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

118. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC related Defendants owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Plaintiff Dale Willis.

119. Specifically, but without limitation:

a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Plaintiff a duty to properly conduct tests to ensure that the methylprednisolone acetate was safe and free of contamination.

120. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through its supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

121. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Plaintiff.

122. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

123. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Plaintiff's injuries.

124. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into him in September 2012.

125. As a direct and proximate result of the negligence of these Defendants, and being injected with contaminated doses of methylprednisolone acetate, Dale Willis has suffered injuries and damages, including but not limited to pain and suffering, emotional distress, anxiety, emotional damage, and has incurred medical and other expenses. Such damages render him no longer able to engage in his daily activities and enjoyment of life.

COUNT II
NEGLIGENCE PER SE
(Against NECC Related Defendants)

126. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

127. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiff a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

128. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

129. Defendants also violated Massachusetts law and its pharmacy licensing obligations.

130. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Dale Willis has suffered injuries and damages as described with particularity, above.

COUNT III
NEGLIGENT SUPERVISION
(Against NECC Related Defendants)

131. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

132. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

133. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

134. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

135. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff, Dale Willis.

136. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Dale Willis has suffered injuries and damages as described with particularity, above.

COUNT IV
PUBLIC NUISANCE
(Against Barry Cadden, Gregory Conigliaro and GDC)

137. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

138. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

139. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

140. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

141. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

142. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

143. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

144. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Plaintiff's injuries.

145. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Dale Willis special injury in that Dale Willis has sustained injuries to his personal health.

146. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Dale Willis has suffered injuries and damages as described with particularity, above.

COUNT V
DECEPTIVE TRADE PRACTICES ACT
(Against NECC Related Defendants)

147. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further alleges:

148. The NECC Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

149. The NECC Related Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act. The NECC Related Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

150. As described herein, the NECC Related Defendants represented that their product had characteristics, uses and benefits that it did not have.

151. As described herein, the NECC Related Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

152. The NECC Related Defendants failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use NECC Related Defendants' product.

153. The NECC Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Plaintiff, constituting a violation of the Act.

154. The NECC Related Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

155. The NECC Related Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

156. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

157. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiff.

158. The NECC Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the product;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

159. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally, the NECC Related Defendants were unethical and unscrupulous, and caused substantial injury to consumers. The NECC Related Defendants engaged in unconscionable actions and course of action.

160. The NECC Related Defendants willfully engaged in the conduct described herein, which they knew were deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

161. The NECC Related Defendants are liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

COUNT VI
PRODUCT LIABILITY CLAIMS
(Against Specialty Surgery Center and Dr. Kenneth Lister)

162. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

163. The MPA injected into Dale Willis's lumbar spine on July 17, 2012 was compounded by NECC.

164. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (Eastern Division) No. 12-19882-HJB.

165. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

166. Plaintiff could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

167. Plaintiff's claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

168. NECC has ceased operations.

169. NECC is unable to pay its debts as they fall due.

170. NECC is unable to pay its debts in the ordinary course of its business.

171. NECC's liabilities exceed its assets.

172. NECC is insolvent as declared by order dated July 24, 2013 in the Bankruptcy Proceeding.

173. Specialty Surgery Center procured the MPA injected into Dale Willis's lumbar spine from NECC.

174. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery Center injected it into Dale Willis's lumbar spine on July 17, 2012.

175. Specialty Surgery Center charged Dale Willis for ESIs administered to Dale Willis.

176. Specialty Surgery Center acted as a seller or distributor of MPA compounded by NECC when it sold and administered ESIs, including Dale Willis.

177. Specialty Surgery Center was engaged in the business of selling MPA compounded by NECC.

178. Accordingly, Specialty Surgery Center is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

179. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiff Dale Willis to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA injected into Dale Willis's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.

180. The MPA that Specialty Surgery Center injected into Dale Willis's lumbar spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

181. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

182. The MPA sold and distributed by Specialty Surgery Center was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery Center breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

183. Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Dale Willis's lumbar spine.

184. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act, T.C.A. § 29-26-101, *et. seq.* Plaintiff has served notice

letters as required by the TMMA, but sixty days haven not yet passed since service of those letters. Plaintiff files this action to preserve her products liability action, and will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

DAMAGES

185. As a direct and proximate result of the Defendants' wrongful conduct as described above, Dale Willis has suffered physical injuries, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.

186. The long term effects of Dale Willis's illness are unknown.

187. Dale Willis remains under the care of physicians. Dale Willis has incurred and continues to incur medical and other expenses.

PUNITIVE DAMAGES

188. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiff therefore is entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

189. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiff's non-economic damages are purportedly capped at $750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.

190. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiff's constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever . . . and shall forever remain inviolate." Therefore, Dale Willis requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

191. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiff is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Dale Willis requests the following relief:

A. A judgment to plaintiff for compensatory damages in excess of $75,000;

B. A judgment for punitive damages in an amount to be determined by the trier of fact;

C. A jury to determine all disputed factual issues;

D. For costs of this cause and reasonable attorneys' fees; and

E. For such further relief as the Court may deem just and proper.

Respectfully submitted,

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